

<b>STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION</b>		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>MD3079</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: B. WING:	(X3) DATE SURVEY COMPLETED  <b>12/07/2012</b>
NAME OF FACILITY <b>UNIVERSITY OF MARYLAND ST. JOSEPH MEDICAL CENTER</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>7601 OSLER DRIVE TOWSON, MD 21204</b>		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY SHOULD BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERRED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 000	<b>INITIAL COMMENTS</b>  On December 5, 6, and 7, ten staff of the Office of Health Care Quality, accompanied by three staff from the Centers of Medicare and Medicaid Services, performed an initial survey of University of Maryland Saint Joseph Medical Center to determine if the hospital was in compliance with the Medicare Conditions of Participation for Acute General Hospitals. The survey included review of 57 closed and open medical records, interviews with staff and patients, observations of the environment of care and of patient care and review of other pertinent records and documents. Based on that survey, the following deficiencies were cited:	A 000	THE UNIVERSITY OF MARYLAND ST. JOSEPH MEDICAL CENTER (THE "HOSPITAL") IS FILING THIS PLAN OF CORRECTION FOR PURPOSES OF REGULATORY COMPLIANCE. THE HOSPITAL IS SUBMITTING THIS PLAN OF CORRECTION TO COMPLY WITH APPLICABLE LAW AND NOT AS AN ADMISSION OR STATEMENT OF AGREEMENT WITH RESPECT TO THE ALLEGED DEFICIENCIES HEREIN.	

Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See reverse for further instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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A 049	<p>481.12(a)(5) MEDICAL STAFF – ACCOUNTABILITY</p> <p>(The governing body must) ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.</p> <p>This STANDARD is not met as evidenced by: Based on staff interviews, policies and procedures, and review of personnel files of the surgical assistants, it was determined that the hospital failed to ensure that the two surgical assistants are directly supervised by a member of the medical staff, that their privileges were not delineated in accordance with the medical staff bylaws, and that annual appraisals were performed by the supervising practitioner as evidenced by:</p> <p>During the interview process with the Director of Surgical Services on 12/6/12 at approximately 2:00 pm, it was revealed that the hospital employs physician assistants and surgical assistants in the cardiac operating room. The surgical assistants are performing open and endoscopic saphenous vein harvesting. Further interview revealed the physician assistants are supervising the surgical assistants during this procedure. The hospital did state that the surgical assistants are graduates from foreign medical schools. The hospital was informed by</p>	A 049	<p>The following actions were taken by the CEO with the approval of the Governing Body who is also responsible for ongoing compliance with this corrective action:</p> <ul style="list-style-type: none"> <li>The Governing Body provides effective oversight for cardiac surgical care through the management of its credentialing, privileging, competence assurance and supervision processes by Senior leaders and Medical Staff. The Medical Staff reports to the Governing Body for the quality of patient care provided and make recommendations for provider privileging.</li> <li>The Medical Staff members are responsible for recommending clinical privileges to the Board, conducting initial and annual competency reviews, and ensuring adherence to the COR supervision requirements.</li> <li>Individuals who are not privileged by the Medical Staff and approved by the Governing Body will not be allowed to perform surgical procedures; however such individuals may serve as Second Assist. The job duties of a Second Assist do not include performing any surgical procedures. The Second Assist job description was modified to accurately reflect the responsibilities for the position.</li> <li>A policy was developed and approved entitled, MS 10 - Surgical Assistant Requirements, that clarifies the requirements for privilege delineation, assurance of competence and direct</li> </ul>	<p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p>

	<p>the surveyor that a physician assistant cannot supervise the surgical assistants since this would be outside their scope of practice. Review of the hospital bylaws revealed that the privileges, skill sets or competency requirements that can be performed by the surgical assistants were not delineated.</p> <p>In addition, on 12/7/12 at approximately 12:10 pm, the Director of Surgical Services and Chief of Cardiac Anesthesia, Associate Director of Cardiac Surgery ICU and President of the Medical Staff stated that he could not validate that the surgical assistants were consistently supervised by the surgeon (100% of the time) as per the job description and COMAS 10.32.16 Petition for Declaratory Ruling. The ruling determined that a surgeon may delegate to a properly trained unlicensed surgical assistant the harvesting of the saphenous vein by either the open or the endoscopic methods during a CABG (Coronary artery bypass grafting) procedure as long as the surgeon is present, scrubbed, and personally performing the CABG procedure. The hospital has no discernible process to validate that supervision is occurring as dictated by the policy and procedure and State Law.</p> <p>Based on review of the personnel files of the two surgical assistants on 12/7/12, it was determined that the Chief Physician Assistant had performed their annual appraisals as it was his signature on the appraisals. There were 5 years of personnel files prior to 2009 that were not available for review to determine when the last appraisal was performed. The personnel files most recently skills/competency evaluation performed by a surgeon was dated 12/7/12 (the day of the personnel file review and last day of the survey). The personnel files lack any documentation of original privileging, on-going education and</p>		<p>supervision of surgical assistants when performing surgical procedures.</p> <ul style="list-style-type: none"> <li>• The revised job description was reviewed and approved by the Chief Medical Officer, Chief of Cardiac Surgery, Chief of Surgery, Director of Surgical Services and V.P. Operations. The revised job description was provided and reviewed with staff</li> <li>• Competencies for the Surgical Assistant "Second Assist" were revised and approved by the Chief Medical Officer, Chief of Cardiac Surgery, Chief of Surgery, Director of Surgical Services and V.P. Operations. The revised competencies for Second Assist were provided and reviewed with staff.</li> <li>• Human Resources tracks annual reviews and competency assessments as noted in policy HR-A23 and notifies department directors of Annual reviews and competency assessment due dates. Compliance with annual reviews and competency assessments is reported to administration and the Board.</li> <li>• The Patient Care Coordinator or designee verifies privileges prior to the start of the case for non-surgeons who will be performing any surgical procedure in the Cardiac Operating Room and notes this on the medical record.</li> <li>• Any concern with privileges is referred immediately to the Director of Surgical Services and the case is stopped until the issue is resolved.</li> <li>• Circulating staff note the surgeon in room time and the surgical assistant start time to demonstrate supervision by the surgeon while the procedure is underway.</li> <li>• Chart audits are conducted for verification of provider privileges and the direct supervision of surgical assistants.</li> <li>• Monthly audit will continue until full compliance is achieved and sustained for a period of 3</li> </ul>	<p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>Effective</p>
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A 115	<p>proctoring of the surgical assistants skill set and competency. This information is to be used to monitor for compliance with supervision and provide documentation regarding competency.</p> <p>See also A 945, A 347</p> <p><b>482.13 PATIENT RIGHTS</b></p> <p>A hospital must protect and promote each patient's rights.</p> <p>This CONDITION is not met as evidenced by: Based on the review of records and interviews with staff, it was determined that the hospital failed to honor the patient's right to make informed decisions about their cardiac surgical care. In three of 57 medical records reviewed (patient #31, patient #34, and patient #35), the hospital failed to ensure surgical consents were complete and properly executed. See the deficiency cited at A 955 and A 131.</p>	A 115	<p>months.</p> <ul style="list-style-type: none"> <li>Results and surgical privilege concerns are reported to the Department of Surgery Quality and Safety Committee, the Medical Executive Committee and the Board.</li> </ul> <p>The following actions were taken by the Chief Medical Officer who is also responsible for ongoing compliance with the corrective action:</p> <ul style="list-style-type: none"> <li>Policy PR 4 - Informed Consent was reviewed and no changes were needed.</li> <li>COR Surgeons and peri-operative staff members were re-educated about requirements to have names of credentialed providers performing procedures on the Operative Invasive Procedure Consent Form #55-2559-dtd 12-2012.</li> <li>COR Surgeons and peri-operative staff were re-educated about the requirement to include Significant Surgical Tasks, such as Endoscopic Vein Harvesting, on the Operative Invasive Procedure Consent Form(55-2559-dtd 12-2012)</li> <li>The "Reasons and Benefits" section of the Operative Invasive Procedure Consent Form #55-2559-dtd 12-2012 was revised to address these issues.</li> <li>The "Risks and Hazards" section of the Operative Invasive Procedure Consent Cardiac Surgery Form #55-2559-dtd 12/2012 was modified to include appropriate terminology.</li> <li>Patient consents forms will be completed prior to procedure.</li> <li>COR staff have been authorized to "stop the line" if the surgical consent is incomplete.</li> <li>Accountability concerns are directed immediately to the Director of Surgical Services and follow chain of command to the Chief of Surgery and ultimately to the Chief Medical Officer.</li> </ul>	<p>Immediately</p> <p>12/10/12</p> <p>12/10/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p>
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A 131	<p>482.13(b)(2) PATIENTS RIGHTS: INFORMED CONSENT</p> <p>The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care.</p> <p>The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.</p> <p>This STANDARD is not met as evidenced by: Based on staff interviews, policies and procedures, observations, medical record review and other pertinent documentation, the hospital failed to ensure that surgical consents for cardiac surgery were properly executed for three of three cardiac surgery patients reviewed. In three of 57 medical records reviewed (patient #31, patient #34, and patient #35), the hospital failed to ensure surgical consents were complete including</p>	A 131	<ul style="list-style-type: none"> <li>100% of the COR surgical consent forms will be audited by the Patient Care Coordinator or designee on the day of surgery to ensure appropriate completion of the consent form prior to the initiation of the cardiac surgical procedure. The PCC reports results weekly to the Director of Surgery. Monthly random chart audits will be utilized when 100% compliance is achieved and sustained for a period of three months.</li> <li>The Director of Surgical Services will report consent audit results to the Department of Surgery Quality &amp; Safety Committee, the Medical Executive Committee and the Board.</li> </ul> <p>The following actions were taken by the Chief Medical Officer who is also responsible for ongoing compliance with the corrective action:</p> <ul style="list-style-type: none"> <li>Policy PR 4 - Informed Consent was reviewed and no changes were needed.</li> <li>COR Surgeons and peri-operative staff members were re-educated about requirements to have names of credentialed providers performing procedures on the Operative Invasive Procedure Consent Form #55-2559-dtd 12-2012.</li> <li>COR Surgeons and peri-operative staff were re-educated about the requirement to include Significant Surgical Tasks, such as Endoscopic Vein Harvesting, on the Operative Invasive Procedure Consent Form(55-2559-dtd 12-2012)</li> <li>The "Reasons and Benefits" section of the Operative Invasive Procedure Consent Form #55-2559-dtd 12-2012 was revised to address these issues.</li> <li>The "Risks and Hazards" section of the Operative Invasive Procedure Consent Cardiac Surgery Form #55-2559-dtd 12/2012 was modified to include appropriate terminology.</li> <li>Patient consents forms will be completed prior</li> </ul>	<p>12/14/12</p> <p>Effective immediately</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p>
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	<p>being informed of the risks and benefits of the procedure and the names of the individuals who would be participating in performing any part of the procedure as evidenced by:</p> <p>Patient #31 was a 65 year old female admitted to the hospital on 12/6/12. The patient's diagnosis included aortic valve stenosis, atrial fibrillation, and patent foramen ovale (PFO, a hole between left and right upper chambers of the heart). Her surgeries included aortic valve replacement, MAZE procedure (surgical procedure to treat rapid heart rate), and closure of the PFO.</p> <p>On 12/6/12, patient #31 had surgery. The consent form included a boxed area for the names of the assisting physician and surgical assistant and the surgical task to be performed. This area was blank as was the surgical task box. The risk and hazards were not delineated; instead the physician wrote "discussed with patient".</p> <p>Patient #34 is a 67 year old male admitted to the hospital on 12/3/12. The patient diagnoses included coronary artery disease and right lower lobe lung nodule. The patient had surgery on 12/6/12. His surgery included quadruple coronary artery bypass grafting (CABG x 4). The surgical consent form lacks the name of the assisting physician and the surgical assistant in the box provided with the surgical tasks to be performed were not written in the box. On the risk and benefit lines, the surgeon wrote "as discussed".</p> <p>Patient #35 was a 60 year old male admitted to the hospital on 12/5/12 with a diagnosis of atherosclerotic coronary artery disease. The patient had surgery on 12/6/12. His surgery included CABG x 5. The consent form lacks the names of the assisting physicians and surgical assistant, again the box is checked for unknown.</p>		<p>to procedure.</p> <ul style="list-style-type: none"> <li>• COR staff have been authorized to "stop the line" if the surgical consent is incomplete.</li> <li>• Accountability concerns are directed immediately to the Director of Surgical Services and follow chain of command to the Chief of Surgery and ultimately to the Chief Medical Officer.</li> <li>• 100% of the COR surgical consent forms will be audited by the Patient Care Coordinator or designee on the day of surgery to ensure appropriate completion of the consent form prior to the initiation of the cardiac surgical procedure. The PCC reports results weekly to the Director of Surgery. Monthly random chart audits will be utilized when 100% compliance is achieved and sustained for a period of three months.</li> <li>• The Director of Surgical Services will report consent audit results to the Department of Surgery Quality &amp; Safety Committee, the Medical Executive Committee and the Board.</li> </ul>	<p>12/14/12</p> <p>12/14/12</p> <p>Effective immediately</p> <p>Effective immediately</p> <p>Effective immediately</p>
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	<p>The surgical task for the assisting physician was blank and in the block for the surgical assistant was written saphenous vein harvest. In the space for the risk and hazards of the procedure was written “discussed with patient and wife” but no specifics.</p> <p>According to interviews with other surgeons, Patients #34 and 35 signed the consent forms one to two days before the procedure which is why no names were placed in the assisting physician and surgical assistant block but the task to be performed should have been written in the box provided.</p> <p>According to the COMAR 10.32.16, Petition for Declaratory Ruling, the operative tasks and the persons delegated to perform those tasks should be delineated on the consent and informed consent should be obtained from the patient.</p> <p>The hospital’s consent for cardiac surgery satisfies the requirements for informed consent regarding the tasks performed by unlicensed assistants, however, the hospital failed to ensure that the surgeons are using the form as designed.</p>			
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A 143	<p>482.13(c)(1) PATIENT RIGHTS: PERSONAL PRIVACY</p> <p>The patient has the right to personal privacy. This STANDARD is not met as evidenced by: Based on observation, interview and review of policy and behavioral health records, it was determined that patient #1 was not afforded personal privacy as is her right.</p> <p>Patient #1 is a 25-year-old female, with a history of depression and self-mutilating behaviors. Patient #1 was voluntarily admitted on 12/4/2012 following significant self-inflicted injuries to the left forearm and calf. On admission, patient #1 was placed on 1:1 observation.</p> <p>During the survey of 12/5/12, patient #1 was observed sitting in the day area with a 1:1 staff. Inquiry regarding unit practices revealed that patient #1 had slept in this area throughout the night and was not provided an area with privacy while she slept.</p> <p>The surveyors reviewed Hospital Policy number APC 7 "Constant Patient Observation " revised</p>	A 143	<p>The following actions were taken by the Director of Nursing for: Psychiatry, MCH and Central Staffing. That individual is also responsible for ongoing compliance with this corrective action:</p> <ul style="list-style-type: none"> <li>• The constant observation patient referenced in the finding was reevaluated by the psychiatrist to assess her ability to be safe in her bedroom.</li> <li>• The patient was moved to her bedroom at night.</li> <li>• The constant observation policy was revised to respect patient privacy and remove the option for constant observation patients to sleep in the day area at night.</li> <li>• The constant observation policy change was approved.</li> <li>• Staff were educated on management of constant observation patients in the patient's bedroom at night while maintaining patient privacy.</li> </ul>			<p>12/5/12</p> <p>12/6/12</p> <p>12/5/12</p> <p>12/5/12</p> <p>12/5/12</p>
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A 143	<p>4/2012 states in part, “2. Multipurpose Room Observation (MPR) a. The patient is limited to the MPR during waking hours and is on strict observation at night. b. Patient may also be requested to sleep with “Bed in hall” at night.”</p> <p>Review of the RN documentation of 12/5/2012 at 3:07 am revealed in part, “She is bed hall w/sitter.” Interview with a staff RN revealed that patient #1 did in fact spend the night sleeping in a reclining lounge chair in a shared common area of the behavioral unit. While patient #1 was 1:1 staffing, she was not afforded privacy when sleeping.</p> <p>Prior to the end of the survey, an administrative team met and has discontinued the practice of having high risk patients sleep in public areas without privacy.</p>	A 143	<ul style="list-style-type: none"> <li>Management of patients may include use of lighting and audio-video cameras.</li> <li>Staff in all areas were educated about patient privacy during morning safety huddle.</li> <li>No patients were adversely affected by this finding. One patient was affected by this finding in Psychiatry, was reevaluated and changes were made to the plan of care for the patient.</li> </ul> <p>Ongoing Nurse Manager and Supervisor rounds have incorporated checking for patients under observation in the hallways. Any non-compliance is addressed immediately through patient reevaluation. Instances of non-compliance are addressed immediately and discussed at morning safety huddle to reinforce the importance of patient privacy and appropriate observation for patients.</p> <p>Safety huddle issues are reported to the Quality and Safety Committee for further evaluation.</p>	<p>12/11/12</p> <p>12/6/12</p> <p>12/11/12</p> <p>12/6/12</p> <p>12/11/12</p>

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A 144	<p>482.13(c)(2) PATIENT RIGHTS: CARE IN SAFE SETTING</p> <p>The patient has the right to receive care in a safe setting.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview and review of patient records, the facility failed to secure laundry detergent on the behavioral health unit where it was accessible to mentally ill patients as evidenced by: During an environmental tour of the behavioral health unit, the day room revealed an open laundry area where patients wash their clothing. Built into the wall of this area is a slant-top bin, approximately 2.5 feet high by 2 feet wide. Upon opening the bin, which had no evidence of a locking mechanism, multiple pounds of dry laundry detergent were observed inside.</p>	A 144	<p>The following actions were taken by the Director of Nursing for, Psychiatry, MCH, Central Staffing. That individual is also responsible for ongoing compliance with this corrective action:</p> <ul style="list-style-type: none"> <li>• The laundry soap powder was immediately removed from the day area.</li> <li>• The laundry soap holder was removed from the wall.</li> <li>• Policy # IC 17 Psychiatry Infection Control was reviewed and revised to include that laundry detergent is secured in a locked cabinet and only distributed by staff for laundry services by patients.</li> <li>• Staff were educated about the dangers of laundry soap powder and the need to store securely.</li> <li>• Staff were also oriented to the new process of obtaining laundry soap powder for patients when needed for laundry service.</li> <li>• No patients were adversely affected by this finding</li> <li>• Staff not following this process receive counseling on compliance with hospital policies and procedures.</li> </ul>	<p>12/5/12</p> <p>12/6/12</p> <p>12/11/12</p> <p>12/5/12</p> <p>12/11/12</p> <p>Effective immediately</p>
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A 144	This represents a potential safety hazard for patients who have been admitted due to dangerousness to self and others. Once identified as a safety issue, the facility enclosed the bin to make it accessible to staff only.	A 144	100% of the time laundry soap is secured in locked cabinet on daily rounds. Instances of unsecured laundry soap are reported through IRIS as safety issues. Monthly rounds will be conducted by the nursing director to ensure that no hazardous chemicals exist on unit. IRIS reports are reviewed by the Psychiatric Quality & Safety Committee monthly and reported to the Quality & Safety Committee.	12/5/12  12/14/12 and monthly thereafter  12/11/12
A 286	482.21(a), (c)(2), (e) PATIENT SAFETY  (a) Standard: Program Scope (1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will...identify and reduce medical errors... (2) The hospital must measure, analyze and track ...adverse patient events...	A 286	The following actions were taken by the Director of Laboratory Services and that individual is responsible for ongoing compliance with this corrective action: <ul style="list-style-type: none"> <li>• Availability &amp; review of PI data, testing reviews, minutes: <ul style="list-style-type: none"> <li>○ Reviewed the stated deficiency with all of Lab Leadership</li> <li>○ Established a standardized way to report each department's PI data, including testing reviews conducted by the technical consultant, back to testing staff. In monthly staff meetings a hardwired agenda point is now PI for that department. Each item on that department's PI dashboard will be discussed.</li> </ul> </li> </ul>	12/5/12
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A 286	<p>(b) Program Activities</p> <p>(2) Performance improvement activities must track medical errors and adverse patient events, analyze their causes and implement preventive actions and mechanisms that include feedback and learning throughout the Hospital.</p> <p>(e) Executive Responsibilities, The Hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following...</p> <p>(3) That clear expectations for safety are established.</p> <p>This STANDARD is not met as evidenced by: Based on review of records, it was determined that the laboratory's quality assurance activities failed to provide adequate feedback for staff to be made aware of the quality assessment findings.</p>	A 286	<ul style="list-style-type: none"> <li>○ PI information reported at staff meetings was written in the minutes</li> <li>○ All staff receive an email with return receipt providing notification that minutes are available and are to be reviewed with a "must read by" date</li> <li>○ Lab Leadership will copy the email and obtain the list of staff that opened the email by "read by" date</li> <li>○ Staff that have not read email (and worked within that time period) receive a first offense - verbal warning; second offense - written warning.</li> <li>○ Staff that had not read email and had not worked in that time period will be monitored to assure they read the email containing new PI data and minutes the next time they work.</li> <li>● Review of QA summaries by pathologists: <ul style="list-style-type: none"> <li>○ The EOC policy has been updated to clearly state the following practice:</li> </ul> </li> </ul>	12/7/12

Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See reverse for further instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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<b>STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION</b>		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>MD3079</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: B. WING:	(X3) DATE SURVEY COMPLETED <b>12/07/2012</b>
NAME OF FACILITY <b>UNIVERSITY OF MARYLAND ST. JOSEPH MEDICAL CENTER</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>7601 OSLER DRIVE TOWSON, MD 21204</b>		
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A 286	<p>Based on record review and interview, the laboratory's quality assessment (QA) program did not include a system to ensure that the testing personnel were informed of QA reviews conducted by the technical consultant (TC). The findings include:</p> <p>The technical consultant for Hematology and Chemistry stated that she would notify the testing personnel via e-mail that the QA minutes were in the communication book in the laboratory. The QA plan did not include a system for documenting that all the appropriate staff had reviewed the QA minutes to ensure that problems and corrective actions are reviewed with the staff members that were not as able to attend the meeting as part of an ongoing in-service program.</p> <p>Further, the laboratory director did not ensure that the quality assessment (QA) reviews were reviewed in a timely manner.</p>	A 286	<ul style="list-style-type: none"> <li>▪ In addition to this downward movement of PI information, there is upward movement of the PI information from our monthly meetings to quarterly reviews with action plans, point persons, and changes in actions if the first plan was not effective.</li> <li>▪ These quarterly reports are to be read, signed and dated by the appropriate pathologist. <ul style="list-style-type: none"> <li>○ Pathologist's signatures and dates of signing are noted on each indicator's quality reports.</li> <li>○ Departmental supervisors assure the pathologist(s) signature is documented.</li> </ul> </li> </ul> <p>Pathologists were re-educated and were provided with the revised policy.</p> <p>No patients were affected by this deficiency.</p>	12/7/12

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A 286	<p>According to the laboratory manager, there are four pathologists who are required to review specific departmental QA summaries. The quarterly QA documents for 2012 were reviewed and showed that one of the four pathologists did not document the date that the QA documents were reviewed.</p> <p>Prior to the conclusion of the survey, the hospital's QA director, along with the Laboratory director, had instituted the use of a checklist to ensure that all laboratory personnel are signing and dating new QA information.</p>	A 286	<ol style="list-style-type: none"> <li>100% of required and available (i.e., not on leave) laboratory staff will review updated PI data and minutes each month.</li> <li>100% of indicator quality reports will be signed by the appropriate pathologist(s) each quarter.</li> </ol> <p>Quality indicator reports are shared at the monthly Laboratory PI meeting. Quarterly, a summary is sent to the VP of Operations to address opportunities for improvement.</p>			12/7/12 and ongoing
VICE PRESIDENT OF OPERATION'S SIGNATURE <b>Craig J. Carmichael</b>			TITLE			(X6) DATE

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A 338	<p>482.22 MEDICAL STAFF</p> <p>The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital.</p> <p>This CONDITION is not met as evidenced by: Based on staff interviews, policies and procedures, and review of personnel files of the surgical assistants, it was determined that the hospital medical staff failed to have a process to review the competencies of two surgical techs who assist in cardiovascular surgery; failed to provide direct physician supervision of the surgical techs as required by their scope of practice; and failed to delineate the privileges of the surgical techs under the medical staff bylaws. See the specific finding under A049, A347, A341, A955, A945 and A959.</p>	A 338	<p>The following actions were taken by the CEO with the approval of the Governing Body who is also responsible for ongoing compliance with this corrective action:</p> <ul style="list-style-type: none"> <li>The Governing Body provides effective oversight for cardiac surgical care through the management of its credentialing, privileging, competence assurance and supervision processes by Senior leaders and Medical Staff. The Medical Staff reports to the Governing Body for the quality of patient care provided and make recommendations for provider privileging.</li> <li>The Medical Staff members are responsible for recommending clinical privileges to the Board, conducting initial and annual competency reviews, and ensuring adherence to the COR supervision requirements.</li> <li>Individuals who are not privileged by the Medical Staff and approved by the Governing Body will not be allowed to perform surgical procedures; however such individuals may serve as Second Assist. The job duties of a Second Assist do not include performing any surgical procedures. The Second Assist job description was modified to accurately reflect the responsibilities for the position.</li> <li>A policy was developed and approved entitled, MS 10 - Surgical Assistant Requirements, that clarifies the requirements for privilege</li> </ul>	<p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p>



			<p>delineation, assurance of competence and direct supervision of surgical assistants when performing surgical procedures.</p> <ul style="list-style-type: none"> <li>• The revised job description was reviewed and approved by the Chief Medical Officer, Chief of Cardiac Surgery, Chief of Surgery, Director of Surgical Services and V.P. Operations. The revised job description was provided and reviewed with staff</li> <li>• Competencies for the Surgical Assistant "Second Assist" were revised and approved by the Chief Medical Officer, Chief of Cardiac Surgery, Chief of Surgery, Director of Surgical Services and V.P. Operations. The revised competencies for Second Assist were provided and reviewed with staff.</li> <li>• Human Resources tracks annual reviews and competency assessments as noted in policy HR-A23 and notifies department directors of Annual reviews and competency assessment due dates. Compliance with annual reviews and competency assessments is reported to administration and the Board.</li> <li>• The Patient Care Coordinator or designee verifies privileges prior to the start of the case for non-surgeons who will be performing any surgical procedure in the Cardiac Operating Room and notes this on the medical record.</li> <li>• Any concern with privileges is referred immediately to the Director of Surgical Services and the case is stopped until the issue is resolved.</li> <li>• Circulating staff note the surgeon in room time and the surgical assistant start time to demonstrate supervision by the surgeon while the procedure is underway.</li> <li>• Chart audits are conducted for verification of provider privileges and the direct supervision of surgical assistants.</li> <li>• Monthly audit will continue until full compliance</li> </ul>	<p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p>
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			<p>is achieved and sustained for a period of 3 months.</p> <ul style="list-style-type: none"> <li>Results and surgical privilege concerns are reported to the Department of Surgery Quality and Safety Committee, the Medical Executive Committee and the Board.</li> </ul>	<p>Effective Immediately</p> <p>12/10/12</p>
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A 341	<p><b>482.22 (a) MEDICAL STAFF CREDENTIALING</b></p> <p>The medical staff must examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates.</p> <p>This STANDARD is not met as evidenced by: Based on staff interviews, policies and procedures, and review of personnel files of the surgical assistants, it was determined that the hospital failed to ensure that the two surgical assistants are directly supervised by a member of the medical staff, and were reviewed for competency on an annual basis as evidenced by:</p> <p>During the interview process with the Director of Surgical Services on 12/6/12 at approximately 2:00 pm, it was revealed that the hospital employs physician assistants and surgical assistants in the cardiac operating room. The surgical assistants are performing open and endoscopic saphenous vein harvesting.</p> <p>Review of the personnel files of the two surgical assistants on 12/7/12 revealed that the Chief Physician Assistant had performed their annual appraisals as it was his signature on the appraisals. There were 5 years of personnel files</p>	A 341	<p>The following actions were taken by the CEO with the approval of the Governing Body who is also responsible for ongoing compliance with this corrective action:</p> <ul style="list-style-type: none"> <li>The Governing Body provides effective oversight for cardiac surgical care through the management of its credentialing, privileging, competence assurance and supervision processes by Senior leaders and Medical Staff. The Medical Staff reports to the Governing Body for the quality of patient care provided and make recommendations for provider privileging.</li> <li>The Medical Staff members are responsible for recommending clinical privileges to the Board, conducting initial and annual competency reviews, and ensuring adherence to the COR supervision requirements.</li> <li>Individuals who are not privileged by the Medical Staff and approved by the Governing Body will not be allowed to perform surgical procedures; however such individuals may serve as Second Assist. The job duties of a Second Assist do not include performing any surgical procedures. The Second Assist job description was modified to accurately reflect the responsibilities for the position.</li> <li>A policy was developed and approved entitled, MS 10 - Surgical Assistant Requirements, that clarifies the requirements for privilege</li> </ul>	<p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p>

	<p>prior to 2009 that were not available for review to determine when the last appraisal was performed as they were sequestered for a litigation case. The personnel files most recent skills/competency evaluation performed by a surgeon was dated 12/7/12 (the day of the personnel file review and last day of the survey). The personnel files lack any documentation of original privileging, on-going education and proctoring of the surgical assistants skill set and competency. This information is being used to monitor for compliance with supervision and provide documentation regarding competency.</p> <p>See also A049 and A945.</p>		<p>delineation, assurance of competence and direct supervision of surgical assistants when performing surgical procedures.</p> <ul style="list-style-type: none"> <li>• The revised job description was reviewed and approved by the Chief Medical Officer, Chief of Cardiac Surgery, Chief of Surgery, Director of Surgical Services and V.P. Operations. The revised job description was provided and reviewed with staff</li> <li>• Competencies for the Surgical Assistant "Second Assist" were revised and approved by the Chief Medical Officer, Chief of Cardiac Surgery, Chief of Surgery, Director of Surgical Services and V.P. Operations. The revised competencies for Second Assist were provided and reviewed with staff.</li> <li>• Human Resources tracks annual reviews and competency assessments as noted in policy HR-A23 and notifies department directors of Annual reviews and competency assessment due dates. Compliance with annual reviews and competency assessments is reported to administration and the Board.</li> <li>• The Patient Care Coordinator or designee verifies privileges prior to the start of the case for non-surgeons who will be performing any surgical procedure in the Cardiac Operating Room and notes this on the medical record.</li> <li>• Any concern with privileges is referred immediately to the Director of Surgical Services and the case is stopped until the issue is resolved.</li> <li>• Circulating staff note the surgeon in room time and the surgical assistant start time to demonstrate supervision by the surgeon while the procedure is underway.</li> <li>• Chart audits are conducted for verification of provider privileges and the direct supervision of surgical assistants.</li> <li>• Monthly audit will continue until full compliance</li> </ul>	<p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p>
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			<p>is achieved and sustained for a period of 3 months.</p> <ul style="list-style-type: none"> <li>Results and surgical privilege concerns are reported to the Department of Surgery Quality and Safety Committee, the Medical Executive Committee and the Board.</li> </ul>	<p>Effective Immediately</p> <p>12/10/12</p>
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A 347	<p><b>482.22 (b) MEDICAL STAFF ACCOUNTABILITY</b></p> <p>The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to the patients.</p> <p>(1) The medical staff must be organized in a manner approved by the governing body.</p> <p>(2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.</p> <p>(3) The responsibility for organization and conduct of the medical staff must be assigned only to an individual doctor of medicine or osteopathy or, when permitted by State law of the State in which the hospital is located, a doctor of dental surgery or dental medicine.</p> <p>This STANDARD is not met as evidenced by: Based on staff interviews, policies and procedures, and review of personnel files of the surgical assistants, it was determined that the hospital failed to ensure that the two surgical assistants are directly supervised by a member of</p>	A 347	<p>The following actions were taken by the CEO with the approval of the Governing Body who is also responsible for ongoing compliance with this corrective action:</p> <ul style="list-style-type: none"> <li>The Governing Body provides effective oversight for cardiac surgical care through the management of its credentialing, privileging, competence assurance and supervision processes by Senior leaders and Medical Staff. The Medical Staff reports to the Governing Body for the quality of patient care provided and make recommendations for provider privileging.</li> <li>The Medical Staff members are responsible for recommending clinical privileges to the Board, conducting initial and annual competency reviews, and ensuring adherence to the COR supervision requirements.</li> <li>Individuals who are not privileged by the Medical Staff and approved by the Governing Body will not be allowed to perform surgical procedures; however such individuals may serve as Second Assist. The job duties of a Second Assist do not include performing any surgical procedures. The Second Assist job description was modified to accurately reflect the responsibilities for the position.</li> <li>A policy was developed and approved entitled, MS 10 - Surgical Assistant Requirements, that clarifies the requirements for privilege</li> </ul>	<p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p>

	<p>the medical staff, and that their privileges were not delineated in accordance with the medical staff bylaws as evidenced by:</p> <p>During the interview process with the Director of Surgical Services on 12/6/12 at approximately 2:00 pm, it was revealed that the hospital employs physician assistants and surgical assistants in the cardiac operating room. The surgical assistants are performing open and endoscopic saphenous vein harvesting. Further interviews revealed the physician assistants are supervising the surgical assistants during this procedure. The hospital did state that the surgical assistants are graduates from foreign medical schools. The hospital was informed by the surveyor that a physician assistant cannot supervise the surgical assistants since this would be outside their scope of practice. Review of the hospital bylaws revealed that the privileges, skill sets or competency requirements that can be performed by the surgical assistants were not delineated.</p> <p>In addition, on 12/7/12 at approximately 12:10 PM the Director of Surgical Services and Chief of Cardiac Anesthesia, Associate Director of Cardiac Surgery ICU and President to the Medical Staff stated that he could not validate that the surgical assistants were consistently supervised by the surgeon (100% of the time) as per the job description and COMAR 10.32.16 Petition for Declaratory Ruling. The ruling determined that a surgeon may delegate to a properly trained unlicensed surgical assistant the harvesting of the saphenous vein by either the open or the endoscopic methods during a CABG (Coronary artery bypass grafting) procedure. The hospital has no discernible process to validate that supervision is occurring as dictated by the policy and procedure and State Law.</p>		<p>delineation, assurance of competence and direct supervision of surgical assistants when performing surgical procedures.</p> <ul style="list-style-type: none"> <li>• The revised job description was reviewed and approved by the Chief Medical Officer, Chief of Cardiac Surgery, Chief of Surgery, Director of Surgical Services and V.P. Operations. The revised job description was provided and reviewed with staff</li> <li>• Competencies for the Surgical Assistant "Second Assist" were revised and approved by the Chief Medical Officer, Chief of Cardiac Surgery, Chief of Surgery, Director of Surgical Services and V.P. Operations. The revised competencies for Second Assist were provided and reviewed with staff.</li> <li>• Human Resources tracks annual reviews and competency assessments as noted in policy HR-A23 and notifies department directors of Annual reviews and competency assessment due dates. Compliance with annual reviews and competency assessments is reported to administration and the Board.</li> <li>• The Patient Care Coordinator or designee verifies privileges prior to the start of the case for non-surgeons who will be performing any surgical procedure in the Cardiac Operating Room and notes this on the medical record.</li> <li>• Any concern with privileges is referred immediately to the Director of Surgical Services and the case is stopped until the issue is resolved.</li> <li>• Circulating staff note the surgeon in room time and the surgical assistant start time to demonstrate supervision by the surgeon while the procedure is underway.</li> <li>• Chart audits are conducted for verification of provider privileges and the direct supervision of surgical assistants.</li> <li>• Monthly audit will continue until full compliance</li> </ul>	<p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p>
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	<p>Based on review of the personnel files of the two surgical assistants on 12/7/12, it was determined that the Chief Physician Assistant had performed their annual appraisals as it was his signature on the appraisals. There were 5 years of personnel files prior to 2009 that were not available for review to determine when the last appraisal was performed as they were sequestered for litigation case. The personnel files most recent skills/competency evaluation performed by a surgeon was dated 12/7/12 (the day of the personnel file review and last day of the survey). The personnel files lack any documentation of original privileging, on-going education and proctoring of the surgical assistants skill set and competency. This information is being used to monitor for compliance with supervision and provide documentation regarding competency.</p> <p>See also A049 and A945.</p>		<p>is achieved and sustained for a period of 3 months.</p> <ul style="list-style-type: none"> <li>Results and surgical privilege concerns are reported to the Department of Surgery Quality and Safety Committee, the Medical Executive Committee and the Board.</li> </ul>	<p>Effective Immediately</p> <p>12/10/12</p>
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A 405	482.23(c)(1) ADMINISTRATION OF DRUGS  Drugs and biological must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice.	A 405	The following corrective actions have been taken by the Director of Nursing for Critical Care and Emergency Services. That individual is also responsible for ongoing compliance with this corrective action: Policies M1- Controlled Substances, M5 – Infection Control of Medications, and M19 – Storage, handling, Security and Disposition of Medications were reviewed on 12/10/2012.	12/10/12

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A 405	<p>(1) All drugs and biological must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.</p> <p>This STANDARD is not met as evidenced by: Based on an interview and tour of the medical surgical intensive care unit (MSICU), it was determined that improper storage of medication, including narcotics, may be occurring as evidenced by:</p> <p>During the site visit, a tour of the MSICU was completed. At the time of the tour, the State surveyor, accompanied by the CMS Consultant, noted a locked wall cabinet in an area between two patient rooms containing two nurse servers.</p>	A 405	<ul style="list-style-type: none"> <li>No changes were needed as policies are compliant with applicable law and regulation.</li> <li>Education was provided for nursing staff to assure adherence to these organizational policies, specifically, the safe handling of narcotic medications to mitigate potential for diversion, on 12/10/2012.</li> <li>Random checks of all locked patient medication drawers in MSICU were instituted to assure appropriate storage of medications on 12/10/2012</li> <li>Nursing staff in Critical Care areas were re-educated regarding medication storage policies and procedures.</li> <li>Staff were reminded that partial narcotic doses are not saved in patient drawers, or any other storage location, and must be wasted using a two person (RN) process to witness wastage per Policy M1. This education was provided to staff on 12/10/12 and reinforced by email with return receipt and unit postings.</li> </ul>	<p>12/10/12</p> <p>12/10/12</p> <p>12/10/12</p> <p>12/6 – 12/11/12</p> <p>12/6 – 12/11/12</p>

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<b>STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION</b>		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>MD3079</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: B. WING:	(X3) DATE SURVEY COMPLETED <b>12/07/2012</b>
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A 405	When the surveyor asked the Charge RN what the cabinet was used for, the RN informed the surveyor that if a dose of Morphine was taken from the Pyxis (medication dispensing machine) and only half of the medication was administered to the patient, the other half would be placed in the wall cabinet. At that time, the RN was informed by the surveyor that this was not an acceptable nursing practice since the correct procedure would require the unused part of the narcotic to be wasted in the presence of two nurses and signed by two nurses as a safety and diversion measure.	A 405	<ul style="list-style-type: none"> <li>▪ Pharmacy instituted a check of 20 random doses of narcotics in MSICU weekly to assure compliance with patient orders and proper wastage of the narcotics.</li> </ul> <p>No patients were adversely affected by this finding.</p> <ol style="list-style-type: none"> <li>1. All available (i.e., not on leave) and applicable nursing staff received the above-noted education on 12/10/12. Those not present will be provided with education upon their return to work and prior to seeing patients.</li> <li>2. Random audits of patient medication drawers were initiated on 12/10/12 and no improperly stored medications or partial doses were found.</li> <li>3. Daily random audits of all patient medication drawers will continue for 3 months or until compliance is sustained for a month.</li> </ol> <p>Pharmacy audits of 20 random doses will continue weekly for 3 months or until compliance is achieved for one month.</p>	<p>12/11/12</p> <p>12/10/12 and ongoing</p> <p>12/10/12 and ongoing</p> <p>ongoing</p>

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A 450	<p>482.24(c)(1) MEDICAL RECORD SERVICES</p> <p>All patient medical record entries must be legible, complete, dated, timed and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures.</p> <p>This STANDARD is not met as evidenced by: Based on a review of 57 medical records, the following 3 examples of illegible handwriting on the medical records were identified as evidenced by:</p> <p>Patient #40 is a 40 year old male who on December 4, 2012 arrived at University of Maryland St. Joseph Medical Center's Emergency Department with a chief complaint of having auditory hallucinations that were telling him to walk in front of a bus. Patient #40 was triaged, placed on suicidal precautions, provided</p>	A 450	<p>The following actions have been taken by the Chief Medical Officer related to the observations of illegible practitioner signatures on medical record entries. That individual is also responsible for ongoing compliance with this corrective action:</p> <ul style="list-style-type: none"> <li>Legibility of physician signatures has been addressed through an electronic solution. In order to facilitate identification and viewing on all units, physician and allied health signatures will be scanned into the Morrissey Credentialing Database which is accessible through the hospital intranet. The process was initiated November 26, 2012. As of 12/11/12, 60% of the active medical staff has completed this signature identification process. The 40% remaining represent practitioners that are not hospital-based and/or do not visit the hospital daily. All medical staff will have completed this signature identification process within 30 days.</li> </ul>	Effective immediately
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A 450	<p>a sitter and examined by the ED Physician. Patient #40 subsequently received a Psychiatric Emergency Consult. However, on further review of the Psychiatric Consult, it was determined that multiple entries by the same physician had been obliterated by scribbling over the erroneous entry, making the entries illegible. The ED Nursing Director, who accompanied the surveyor was made aware of the deficient practice at the time of the record review. The Assistant Head of Psychiatry was subsequently made aware of the obliterations and sent an email to the physician reminding him that the obliterations were unacceptable.</p> <p>Patient #41 is a 63 year old male with a history of Degenerative Joint Disease who on December 6, 2012 underwent a total hip replacement. On review of the medical record, specifically Pre-Anesthesia Evaluation, the Anesthesia Consent, Anesthesia Record, and Standing Orders Form, it was determined that the anesthesiologist and</p>	A 450	<ul style="list-style-type: none"> <li>Staff and physicians were oriented to the electronic signature files in November 2012. Re-education was provided through organization-wide messaging and one to one demonstration on December 6, 2012.</li> <li>The Medical Staff Office tracks medical staff information through Morrissey and reports issues with the signature file implementation.</li> <li>Unit clerks under the supervision of the Patient Care Coordinators were charged with concurrently reviewing medical records for illegible signatures during their daily activities with patient records. They have continued to copy unclear documentation and fax it to the Medical Staff Officer for review by the appropriate Clinical Chief.</li> </ul>	<p>12/6/12</p> <p>12/6/12</p> <p>12/11/12</p>

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A 450	<p>physician signatures were illegible. At the time of the record review, staff members on the Orthopedic Unit were also unable to determine the physician's signatures via the hospital's electronic "look up". In addition, on further review of the anesthesia record (page 2 of 2), sections of the form labeled "witness for controlled substance waste, transported to, and post-op disposition", the signatures and printed names of the staff member(s) who documented in those sections are illegible.</p> <p>Patient #42 is a 56 year old male who on 12/6/12 underwent a Lumbar Spine Fusion for Degenerative Disc Disease. Review of the Pre Anesthesia Evaluation and Anesthesia Consent Form indicate that the anesthesiologist signatures are illegible. On review of the Occupational Therapy Evaluation and Discharge Summary on 2 of 3 pages of the summary that require the therapist's signature, the therapist only placed initials. In addition, further review of the</p>	A 450	<ul style="list-style-type: none"> <li>HIM staff have included in their discharge analysis a review of medical orders for signature legibility. HIM copies the documentation and faxes it to the Medical Staff Office. The Medical Staff Office sends the documentation to the appropriate Clinical Chief for personal interaction. The Chief provides information on the requirements for legibility and addresses any barriers the provider has in meeting these requirements. The Medical Staff Office retains a copy of the documentation for the providers quality file.</li> <li>Continued illegibility of three or more instances within a 3 month period will constitute a formal letter to the provider from the appropriate Clinical Chief with a copy to the quality file in the Medical Staff Office and become part of the provider's ongoing professional practice evaluation process.</li> </ul>	<p>12/11/12</p> <p>12/10/12</p>

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A 450	<p>Evaluation and summary indicates that page 2 of 3 has the wrong sticker affixed to the page. The sticker includes the wrong patient's name, medical record identification number and the wrong physician's name.</p> <p>Patient #43 is a newborn infant admitted to the Neonatal Intensive Care Unit (NICU) on 12/2/12 post-delivery with meconium aspiration and to rule out sepsis. Patient #43 had also began to show signs of possible withdrawal symptoms which were related to medications consumed by the infant's mother during her pregnancy. On review of the medical record, specifically the Physician interdisciplinary progress notes, it was determined that the Neonatologist signature was illegible. In addition, the surveyor and members of the NICU staff were unable to read the progress note without having the physician called to the NICU to read the note in person.</p>	A 450	<ul style="list-style-type: none"> <li>The Medical Staff Office tracks and trends reported data and provides a summary report to the Medical Executive Committee through existing committee structures to the Board.</li> </ul> <p>The following actions have been taken by the CMO related to the observations of inappropriate documentation for errors (i.e., cross-outs, write-overs, scratch-outs). The CMO is also responsible for ongoing compliance with this corrective action.</p> <ul style="list-style-type: none"> <li>The policy on medical record documentation, IM 19 "Correction of Errors in the Medical Record" was reviewed and no changes were needed. Staff and physician education had been provided on IM 19 in October 2012 when the most recent policy changes were made. Messages were sent to medical staff from the VPMA on December 6, 2012 to review expectations for error correction in the medical record. Health Information Management staff were asked to assist in the identification of inappropriate documentation to assure individual consultation.</li> </ul>	<p>12/7/12</p> <p>12/6/12</p>
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A 450		A 450	<p>The following actions related to the Occupational Therapy documentation were taken by the Director of Rehabilitation Services who is also responsible for ongoing compliance with this corrective action.</p> <ul style="list-style-type: none"> <li>• The Policy for medical record documentation, IM 3 entitled, "Timeframe for Entry of Significant Clinical Data" reaffirms that all entries in the medical record must be timed, dated and properly authenticated.</li> <li>• Occupational Therapists and Physical Therapists were educated about the importance of properly authenticating all entries in the medical record in November 2012.</li> <li>• Re-education was provided for staff on 12/12/2012.</li> <li>• Individual counseling was provided to OT referenced in the finding on 12/12/12</li> <li>• All staff were reminded about the importance of assuring correct patient identification for documentation by affixing appropriate patient identification labels to patient documents.</li> </ul> <p>Monitor OT and PT Evaluation and Discharge Services Forms for signature and correct patient identification for a period of three months or until compliance is sustained compliance.</p>		<p>12/12/12</p> <p>11.13.12</p> <p>12/12/12</p> <p>12/12/12</p> <p>12/12/12</p> <p>12/12/12</p>

			Results will be reported to the Department Director and to the Quality Committee.	12/12/12
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A 467	<p>482.24(c)(2)(vi) CONTENT OF RECORD – OTHER INFORMATION</p> <p>[All records must document the following, ask appropriate:] All practitioner's orders, nursing notes, reports of treatment, medication records, radiology and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.</p> <p>This STANDARD is not met as evidenced by: Based on review of 57 patient records, the facility failed to document allergies consistently through the record of Patient #2 as evidenced by:</p> <p>Patient #2 is a 37-year-old female with a history of cellulitis who on 12/2/2012, went to the Emergency Department (ED) complaining of left groin pain. The ED found Patient #2 to have a fever of 104 degrees F and an open wound to her right heel.</p> <p>ED nursing documentation of 1235 reveals allergies of "Salicylates; Pyrazoles; NSAIDS (Non-Steroidal Anti-Inflammatory); (sic) ibuprophen; Wasp Venom."</p>	A 467	<p>The following actions were taken by the Chief Nursing Officer to ensure consistency of allergy documentation in the medical record. The CNO is also responsible for ongoing compliance with this corrective action.</p> <ul style="list-style-type: none"> <li>The Chief Medical Officer issued an allergy alert to all Emergency Department Physicians and staff regarding the importance of assuring consistent allergy information on ED records.</li> <li>The proposal for the new process will be presented at Medical Executive Committee for input and support at the next meeting.</li> <li>The Chief Nurse, Chief Medical Officer, Director of Hospitalists and the Director of Pharmacy collaborated to develop and approve a standardized approach similar to the medication reconciliation process.</li> <li>M 20 - Medication Reconciliation Policy was reviewed and no revisions were made.</li> <li>The Admission Medication Reconciliation form was modified to allergies as an active component of medication reconciliation.</li> <li>An IT work order was submitted to change the electronic record to create a separate allergy section that serves as the area to go to for this information.</li> <li>The prescriber reviews and signs the medication reconciliation demonstrating agreement with</li> </ul>	<p>12/11/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/11/12</p> <p>12/14/12</p> <p>12/14/12</p>

			<p>the captured information.</p> <ul style="list-style-type: none"> <li>• If the information needs to be modified, the prescriber will make appropriate changes on the form.</li> <li>• Pharmacy updates allergies in the electronic record.</li> <li>• Discrepancies are addressed with the patient and attending physician.</li> <li>• Education about the new process will be provided when the electronic record change is complete.</li> </ul>	<p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>Upon IT completion</p>
			<p>Random medical record selection is used to review 30 records per week for allergy consistency.</p> <p>Random audits will continue for 3 months or until compliance is sustained for one month.</p> <p>Audit results are reported to Medication Safety Committee and Quality Safety Council monthly.</p>	<p>12/10/12</p> <p>Ongoing</p> <p>Ongoing</p>
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A 467	The ED "General Medical" form on which the ED physician documents his assessment, revealed two check boxes under "Allergies". One box may be checked for "NKDA" (no known drug allergies) and one box may be checked for "see RN notes". Neither box was checked by the physician.  Following admission, the H&P (history and physical) of 12/01/2012 revealed an area entitled, "Drug Allergies". Under this heading, the attending physician wrote "No drug allergies".  While Patient #2 received pain medication containing acetaminophen and received none of the medications to which she was allergic, two physicians failed to acknowledge that Patient #2 had medication allergies as noted by the RN.	A 467		
A 701	482.41(a) MAINTENANCE OF PHYSICAL PLANT	A 701		

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A 701	<p>The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.</p> <p>This STANDARD is not met as evidenced by: During inspection of an operating room, the surveyor determined that the top surface of the anesthesia machine has not been cleaned and contained a significant accumulation of dust.</p> <p>On 12/5/12, during a tour of the facility surgical areas, an operating room was observed for cleanliness. A finger drawn over the top of the light-colored anesthesia machine revealed a layer of dust visible on the drawn finger. Additionally, once disturbed, particles of dust were observed to fall from the machine's top surface towards the floor. The proximity of a dusty anesthesiology machine to a surgical field is a risk to the surgical patient.</p>	A 701	<p>The following corrective actions have been taken by the Director of Environmental Services who is also responsible for ongoing compliance with this corrective action</p> <ul style="list-style-type: none"> <li>• Corrective actions were immediately taken with all operating room EVS staff educated to the changes.</li> <li>• The Terminal Cleaning protocol was reviewed and necessary changes were made to ensure that dusting is completed in all operating rooms specifically the anesthesia machines.</li> <li>• The cleaning protocol was reviewed with the director of surgical services and coordinator of infection prevention services to ensure appropriateness.</li> <li>• EVS and Anesthesia tech staff were re-educated about cleaning and dusting procedures.</li> <li>• EVS staff dust equipment nightly and anesthesia techs clean the machines between each case.</li> <li>• Terminal Cleaning Checklist is completed daily by EVS Supervisor.</li> <li>• The revised process was implemented on 12/12/2012</li> </ul> <p>The EVS supervisor completes the daily checklist for terminal cleaning.</p> <p>The EVS supervisor addresses any non-compliance with EVS staff and Anesthesia Techs. This was initiated on</p>	<p>12/11/12</p> <p>12/7/12</p> <p>12/11/12</p> <p>12/11/12</p>

			<p>12/11/12.</p> <p>Every two weeks, terminal cleaning checklists results are reviewed with the Clinical Nurse Manager of the GOR/COR.</p>	
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If continuation sheet Page 40 of 66

			<p>needed.</p> <ul style="list-style-type: none"> <li>○ Policy EC-ME 2 Medical Equipment Purchase was reviewed and no changes were needed.</li> <li>○ The Rehabilitation Equipment Management policy was developed to assure safe functioning equipment in Rehab and infusion areas. Included in this policy are initial inspection of patient equipment, sticker identifications for safety check, ongoing monitoring within the department for potential safety issues and checking equipment prior to use with the patient.</li> <li>○ This policy was approved 12/11/2012.</li> </ul> <ul style="list-style-type: none"> <li>• A patient equipment check sheet was developed to log weekly equipment checks in each area.</li> <li>• Staff were educated about routinely conducting equipment checks and logging safety checks.</li> <li>• Staff were educated about the new process for patient equipment checking and their roles and responsibilities for taking items out of use when broken or without safety stickers, in providing weekly safety checks and in checking equipment prior to use with patients.</li> <li>• A hospital wide investigation is underway to identify areas where patient equipment may be used and is not addressed through Clinical Engineering or Facilities at time of purchase; this will be completed within 30 days.</li> </ul>	<p>12/10/12</p> <p>12/10/12</p> <p>12/11/12</p> <p>12/11/12</p>
<p>VICE PRESIDENT OF OPERATION'S SIGNATURE <b>Craig J. Carmichael</b></p>			<p>TITLE</p>	<p>(X6) DATE</p>

<b>STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION</b>		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>MD3079</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: B. WING:	(X3) DATE SURVEY COMPLETED <b>12/07/2012</b>
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A 724	inspection and maintenance of all patient care equipment including medical devices, is important in ensuring quality patient safety. The findings were: 1. Observation of the 6West Inpatient Rehabilitation Service on 12/05/12 at 1PM revealed that the room was rectangular in shape and contained an Occupational Treatment Area (OTA) on the right side upon entry. Crutches (used and new to be given the patient) were hung on the wall just before the OTA. On the left wall just past the work station was a wall that had multiple pieces of patient physical therapy equipment hung on the wall that consisted of rolling walkers, walkers and canes. By the windows was an adjustable table used for car transfer training, a staircase (wooden) and a Hi-Low Treatment Table.	A 724	Weekly patient equipment safety logs are used properly by staff.  Monthly review by Department Manager to assure ongoing compliance.  Pharmacy hood cleaning logs are monitored by the Director of Pharmacy  Patient equipment issues reported monthly to environment of care committee.	12/11/12  12/11/12  12/11/12

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A 724	<p>The wooden training staircase (plywood/hard wood) had a multiple bolted (wooden) handrail around the entire apparatus which when touched was secure and non-splintered. At the front bottom left-hand corner/base of the staircase was a circular half dollar size missing (top) layer of plywood. This surface is: 1) not a cleanable and disinfectable surface and 2) poses a potential risk of developing a "splintering hazard" to both patient and staff who are exposed and unprotected toe/toes or other body part should have contact with the current surface integrity. Further inspection of the equipment revealed that the rolling walkers and walkers had green stickers indicating property of the hospital. The adjustable training table, staircase and Hi-Low Treatment Table lacked any sticker of a check by the hospital's bioengineering staff.</p> <p>Interview of the Senior Physical Therapist (SL) during PM tour of the Inpatient Rehabilitation</p>	A 724		

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A 724	revealed that: 1) a weekly inspection of all of the equipment was being conducted, however, there has not been a log maintained by staff to reflect this ongoing monitoring process.  Observation of the Outpatient Infusion Center/Service on 12/06/12 at 7:15AM revealed that the center had a series of treatment pods. Each pod consisted of four (4) examination rooms or a combination of working examination rooms with other examination rooms converted into physician work/consultative space (depending on the physician). The examination rooms used for direct patient care contained electric chair/exam table and allowed a patient to sit upright as if a comfortable soft leather chair or to be reclined into a supine position for treatment. Observation of each of these tables during the tour revealed that these tables lacked a hospital bioengineering sticker or evidence of preventative maintenance check. Interview of the Infusion Nursing Staff during the tour revealed that on occasion the examination table paper has	A 724					

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A 724	<p>become “hung up” in the table during use. Additional interview of the Infusion Nursing Staff also indicated that they do not conduct a routine inspection of the examination chair/tables used in this area.</p> <p>Observation and interview of the Outpatient Infusion Center/Service Pharmacy Staff (pharmacist and medication pharmacy technician) revealed that the hood (where medications are compounded in a sterile environment) is decontaminated every morning using a two(2) step system: (1) all surfaces are wiped down with a safe decontaminate product and (2) wiped down with water, followed with a final wipe of alcohol. Interview of the medication pharmacy technician pertaining to the maintenance of a cleaning log showed the only log maintained is a temperature log, not a cleaning log. In the afternoon of 12/06/12, the Clinical Placement/Nursing Supervisor [IS] provided the surveyor with a copy of a</p>	A 724		

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A 724	<p>“Documentation of Cleaning Lamimar Flow Hood Work Surface” which indicated that the hood was noted as checked and cleaned by staff initials on 12/03/12 – 12/06/12. The Clinical Placement/Nursing Supervisor also mentioned that the medication pharmacy technician interviewed by the surveyor was “on loan” from another area and that the cleaning log had been located.</p> <p>Failure by the hospital staff to: 1) conduct periodic inspections of patient care equipment (including preparatory areas), 2) maintaining timely logs of these inspections, and 3) having all staff aware of the (5) W(s)-who, what, where, when and why is an integral part of implementing a preventive maintenance plan to ensure an acceptable level of safety.</p> <p>Based on observation it was determined that facility staff failed to maintain the facility to ensure the safety of the patient.</p>	A 724				

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A 724	<p>On December 5, 2012, the surveyor accompanied by the food service director, the dietician and the safety officer observed the following concerns in the main kitchen:</p> <ol style="list-style-type: none"> <li>1. The exhaust vent in the janitor's closet was not removing air from the room.</li> <li>2. The caulking above the splashboard for the garbage grinder in the pot room was moldy.</li> </ol> <p>On December 5, 2012, the surveyor accompanied by the safety officer and the interim manager of clinical engineering noted the following concerns in ancillary and patient areas of the facility:</p> <ol style="list-style-type: none"> <li>1. Basement Floor (a) Laundry and Linen Break Room – there were numerous old mouse droppings and other debris behind cabinets and the refrigerator; (b) Trash Chute Room, West – liquid waste and debris on floor; and (c) Main</li> </ol>	A 724	<p>The following actions were taken by the Director of Facilities to correct issues identified during building tours. The Director of Facilities is also responsible for ongoing compliance with this corrective action</p> <p><u>Main Kitchen:</u></p> <ul style="list-style-type: none"> <li>• Adjustment was made to exhaust. Surveyor Larry Pilson confirmed exhaust is present. Include task of verifying exhaust in <b>monthly</b> PM schedule via TMS Four Rivers software.</li> <li>• Caulk was replaced in the area. Dietary staff will monitor area for cleanliness. Add to Dietary checklist.</li> </ul> <p><u>Basement Floor:</u></p> <ul style="list-style-type: none"> <li>• The floor was thoroughly cleaned and is cleaned on a weekly basis. EVS to perform daily check.</li> <li>• Chute room was thoroughly cleaned and painted.</li> <li>• Room is cleaned on a daily basis. Chute is cleaned quarterly. Added to EVS daily checklist.</li> <li>• Chute room was thoroughly cleaned and painted.</li> <li>• Lighting fixtures were cleaned and new lamps installed. Exhaust vent was cleaned. Surveyor, Larry Pilson confirmed that work was complete.</li> <li>• Room is cleaned on a daily basis. Chute is cleaned quarterly. Added to EVS daily checklist.</li> </ul> <p><u>Ground Floor:</u></p> <ul style="list-style-type: none"> <li>• Exhaust vent was adjusted and air is being</li> </ul>	<p>12/6/12</p> <p>12/6/12</p> <p>12/6/12</p>

			<p>removed from the space. Surveyor, Larry Pilson confirmed. Included task of verifying exhaust in <b>monthly</b> PM schedule via TMS Four Rivers software.</p> <ul style="list-style-type: none"> <li>The electrical closets were cleaned. Surveyor, Larry Pilson confirmed.</li> </ul> <p><u>Fifth Floor:</u></p> <ol style="list-style-type: none"> <li>Adjustment was made to exhaust in janitor's closet and air is being removed from the janitor's closet. Include task of verifying exhaust in <b>monthly</b> PM schedule via TMS Four Rivers software.</li> </ol>	12/6/12
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A 724	Hospital, Clear Bag Chute Room – the room was not clean, the walls were not clean and are not smooth and cleanable, the lighting in this room is dim and the exhaust vent was dusty.	A 724	1. Proper exhaust added to <b>monthly</b> PM schedule and tracked through TMS Four Rivers software to assure ongoing compliance.	12/6/12
	2. Ground Floor (a) Emergency Room, Soiled Utility Room – the exhaust vent was not removing air from the room; and (b) the floors in the electrical closets were not clean.		2. Cleanliness issues to be maintained through daily and weekly EVS and Dietary rounds.	12/6/12
	3. Fifth Floor, janitor's closet adjacent to Room 511 – the exhaust vent was not removing air from the room.		3. Any variances noted during <b>monthly</b> PM rounds and significant issues of non-compliance noted during daily Kitchen and EVS rounds are reported to the Environment of Care Committee and up through the Quality Committee.	12/6/12
A 940	482.51 SURGICAL SERVICES  If the hospital provides surgical services, the services must be well-organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.  This CONDITION is not met as evidenced by: Based on interviews with staff, reviews of policy, procedures and 3 patient medical records, it was determined that the Condition of Surgical	A 940	The following actions were taken by the CEO with the approval of the Governing Body who is also responsible for ongoing compliance with this corrective action: <ul style="list-style-type: none"> <li>The Governing Body provides effective oversight for cardiac surgical care through the management of its credentialing and privileging processes by Senior leaders and Medical Staff.</li> <li>Surgical Assistants who are not privileged by the Medical Staff and approved by the Governing Body will not be allowed to perform surgical procedures; however such individuals may serve as Second Assist. The job duties of a Second Assist do not include performing any surgical</li> </ul>	12/13/12  12/14/12

	<p>Services was not as evidenced by:</p> <p>The failure to have a properly executed and complete informed consent for the 3 cardiac surgical procedures reviewed as outlined under A0955:</p> <p>The failure to have a complete operative report that delineates who performed each part of the procedure as identified under A0959; and</p> <p>The failure to provide oversight and credentialing of the surgical technicians who assist in the cardiac surgical procedures as noted in A0945.</p>		<p>procedures. The Second Assist job description was modified to accurately reflect the responsibilities for the position.</p> <ul style="list-style-type: none"> <li>• A policy was developed and approved entitled, MS 10 - Surgical Assistant Requirements that clarifies the requirements for credentialing, Medical Staff granting of privileges, assurance of competence and personal supervision of surgical assistants when performing surgical procedures.</li> <li>• The revised job description was reviewed and approved by the Chief Medical Officer, Chief of Cardiac Surgery, Chief of Surgery, Director of Surgical Services and V.P. of Operations. The revised job description was provided to and reviewed by the staff.</li> <li>• Competencies for the Surgical Assistant "Second Assist" were revised and approved by the Chief Medical Officer, Chief of Cardiac Surgery, Chief of Surgery, Director of Surgical Services and V.P. of Operations. The Second Assist competencies were provided to and reviewed by the staff.</li> <li>• The Second Assist competencies were completed by the Chief of Cardiac Surgery and discussed with staff.</li> <li>• Human Resources tracks annual reviews and competency assessments as noted in policy HR-A23 and notifies department directors of Annual reviews and competency assessment due dates. Compliance with annual reviews and competency assessments is reported to administration and the Board.</li> <li>• The Patient Care Coordinator or designee verifies privileges prior to the start of the case for non-surgeons who will be performing any surgical procedure in the Cardiac Operating Room and notes this on the intra-operative record.</li> <li>• Any concern with privileges is referred immediately to the Director of Surgical Services and the case is stopped until the issue is resolved.</li> </ul>	<p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p>
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			<ul style="list-style-type: none"> <li>• Circulating staff note the surgeon in room time and the surgical assistant start time to demonstrate supervision by the surgeon while the procedure is underway.</li> <li>• Chart audits are conducted for verification of non-surgeon privileges and the direct supervision of surgical assistants. Monthly audits will continue until full compliance is achieved and sustained for a period of 3 months.</li> <li>• Results and surgical privilege concerns are reported to the Department of Surgery Quality and Safety Committee, the Medical Executive Committee and the Board.</li> <li>• Reviewed the stated deficiency with the Chief of Surgery and the Chief of Cardiac Surgery.</li> <li>• Supervision of surgical assts was clarified and reinforced with the Chief of Cardiac Surgery and the surgical assistants.</li> <li>• The need for the Surgeon to be present and scrubbed in the room was clarified when surgical assistants perform vein harvesting.</li> <li>• OR staff were authorized to "stop the line" if the surgeon is not present and the surgical assistant is ready to begin</li> <li>• The intra-operative record was modified to create a place for the circulator to document Surgeon in Room Time and Surgeon Out Room time.</li> <li>• The intra-operative record was modified to create a place for the circulator to document vein harvesting start time and vein harvesting end time.</li> <li>• Staff education for new documentation process for supervision provided to staff present and will be revisited at start of each procedure with surgical assistants providing vein harvesting, until all staff and physicians know new process.</li> <li>• The Chief of Cardiac Surgery was in-serviced regarding the need for accurate documentation</li> </ul>	<p>12/14/12</p> <p>Reporting to the Board begins effective immediately</p> <p>12/13/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p>
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			<p>of the significant surgical tasks performed by other practitioners involved in the case, such as Endoscopic Vein Harvesting by surgical assistants or physician assistants.</p> <ul style="list-style-type: none"> <li>• COR Circulators were in-serviced regarding the need for accurate documentation of the tasks performed by the Physician Assistants on the intra-operative record.</li> <li>• Staff and surgeons present were in-serviced about documentation requirements.</li> <li>• Refresh staff prior to start of each case until all surgeons and circulators have implemented new documentation process.</li> </ul> <p>The PCC or designee is responsible for the following audits:</p> <ul style="list-style-type: none"> <li>• 100% of intra-operative documentation is audited for presence of significant surgical tasks by other practitioners on the day of surgery to assure appropriate completion of the COR documentation.</li> <li>• Incomplete documentation is completed with late entry process.</li> <li>• Daily audits continue until 100% compliance is achieved and sustained for one month.</li> <li>• Monthly chart audits will be utilized when daily audits demonstrate compliance with documentation requirements.</li> <li>• 100% of physician operative documentation is audited for evidence of the techniques, findings and tissues removed or altered and the documentation of significant tasks performed by assistants during the operation.</li> </ul> <p>Report compliance results to the Director of Surgery, Department of Surgery Quality and Safety Committee, Medical Executive Committee and the Board of Directors. Quality Committee Compliance issues are reported to the Chief Medical Officer for resolution.</p>	<p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>Reporting to the Board begins effective immediately</p> <p>12/11/12</p> <p>12/11/12</p> <p>12/6/12</p> <p>12/6/12</p> <p>12/11/12</p> <p>12/11/12</p>
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A 945	482.51(a)(4) SURGICAL PRIVILEGES  Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of	A 945	See also A 115.  The following actions were taken by the Director of Surgical Services, who is also responsible for ongoing compliance with this corrective action: <ul style="list-style-type: none"><li>• Reviewed the stated deficiency with the Chief of Surgery and the Chief of Cardiac Surgery.</li></ul>	12/12/12
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			<ul style="list-style-type: none"> <li>Supervision of surgical assts was clarified and reinforced with the Chief of Cardiac Surgery and the surgical assistants.</li> </ul>	12/6/12
			<ul style="list-style-type: none"> <li>The need for the Surgeon to be present and scrubbed in the room was clarified when surgical assistants perform vein harvesting.</li> </ul>	12/6/12
			<ul style="list-style-type: none"> <li>OR staff were authorized to "stop the line" if the surgeon is not present and the surgical assistant is ready to begin</li> </ul>	12/11/12
			<ul style="list-style-type: none"> <li>The intra-operative record was modified to create a place for the circulator to document Surgeon in Room Time and Surgeon Out Room time.</li> </ul>	12/11/12
			<ul style="list-style-type: none"> <li>The intra-operative record was modified to create a place for the circulator to document vein harvesting start time and vein harvesting end time.</li> </ul>	12/11/12
			<ul style="list-style-type: none"> <li>Staff education for new documentation process for supervision provided to staff present and will be revisited at start of each procedure with surgical assistants providing vein harvesting, until all staff and physicians know new process.</li> </ul>	12/7/12

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<b>STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION</b>		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>MD3079</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: B. WING:	(X3) DATE SURVEY COMPLETED <b>12/07/2012</b>
NAME OF FACILITY <b>UNIVERSITY OF MARYLAND ST. JOSEPH MEDICAL CENTER</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>7601 OSLER DRIVE TOWSON, MD 21204</b>		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY SHOULD BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERRED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 945	<p>practitioners specifying the surgical privileges of each practitioner.</p> <p>This STANDARD is not met as evidenced by: Based on staff interviews, along with review of policies and procedures, medical records and other pertinent documentation, the hospital failed to ensure that the surgical first assistants (FA) were being supervised by the surgeons per hospital policy and procedure and in accordance with scope of practice and other State laws and regulations.</p> <p>During an interview on 12/6/12 at approximately 2:00PM with the Director of Surgical Services, he stated that the hospital employs physician assistants (PAs) and surgical assistants in the cardiac operating room. The surgical assistants perform open and endoscopic saphenous vein harvesting from a patient's leg for use during cardiac bypass surgery (CABG) and that the</p>	A 945	<p>The PCC or designee are responsible for:</p> <ul style="list-style-type: none"> <li>• Daily monitoring was instituted to assure supervision is active during harvesting procedures until compliance is achieved.</li> <li>• Daily review of intra-operative report was instituted to capture surgeon and surgical assistant room times until compliance is achieved.</li> <li>• Ongoing monthly audits continue for 3 months or until compliance is sustained for at least one month.</li> <li>• Audit findings will be reported to the Director of Surgical Services.</li> </ul> <p>Monthly reporting of supervision compliance to the Department of Surgery Quality and Safety Committee, Medical Executive Committee and the Board of Directors.</p>	<p>12/12/12</p> <p>Effective immediately</p>
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A 945	surgical assistants were supervised by the surgical PAs. The hospital was informed by the surveyor that it is outside the scope of practice for the PAs to supervise the surgical assistant, and the surgical assistant must be supervised by the surgeon per State law and regulations. In addition, in another interview on 12/7/12 at approximately 12:10PM, the Director of Surgical Services, the Chief of Cardiac Anesthesia, the Associate Director of Cardiac Surgery ICU and President of the Medical Staff stated that they could not validate that the surgical assistants were supervised by the surgeon 100% of the time as per the job description and COMAR (Code of Maryland Regulations) 10.32.16, Petition for Declaratory Ruling. This ruling determined that a surgeon may delegate to a properly trained unlicensed surgical assistant the harvesting of the saphenous vein by either the open or the endoscopic methods during a CABG procedure. In interviews with the executive staff on 12/7/12	A 945	<p>The following actions were taken by the Director of Human Resources to assure competency assessment for surgical assistants. The Director of HR is also responsible for ongoing compliance with this corrective action,</p> <ul style="list-style-type: none"> <li>• Policy HR-A23 Employee Competency Assessment was revised to require that competency assessments are submitted with annual performance reviews.</li> <li>• Surgical Assistant job descriptions were revised to clarify reporting relationships; administrative reporting to OR Manager, clinical reporting to Chief of Cardiac Surgery.</li> <li>• New job descriptions were provided for the surgical assistants-second assist.</li> <li>• Roles and responsibilities were clarified with the Chief of Cardiac Surgery and the Surgical Assistants-Second Assist.</li> <li>• Medical Staff supervision responsibilities for unlicensed providers were reaffirmed with the Chief of Cardiac Surgery.</li> <li>• The Chief of Cardiac Surgery assessed competency for the surgical assistants-second assist.</li> </ul>	<p>12/10/12</p> <p>12/10/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p>
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A 945	they stated that the PAs had not supervised the surgical assistants since 2009.  However, in reviewing the personnel files of two surgical assistants on 12/7/12, it was determined based on signatures, that the Chief Physician Assistant had performed their annual performance appraisals. Five years of personnel files from prior to 2009 were not available for review but the most recent skills/competency evaluation performed by a surgeon was dated for 12/7/12, (the day of the personnel file review and last day of the survey).  See also Tag A-0955	A 945	<ul style="list-style-type: none"> <li>Human Resources tracks annual reviews and competency assessments as noted in policy HR-A23 and notifies department directors of Annual reviews and competency assessment due dates. Compliance with annual reviews and competency assessments is reported to administration and the Board.</li> </ul>	Effective immediately
A 955	482.51(b)(2) INFORMED CONSENT  A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies.	A 955		

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A 955	<p>This STANDARD is not met as evidenced by: Based on staff interviews, policies and procedures, observations, medical record review and other pertinent documentation, the hospital failed to ensure that surgical consents were complete and properly executed for three of three cardiac surgery patients reviewed. In three of 57 medical records reviewed (patient #31, patient #34 and patient #35), the hospital failed to ensure surgical consents were complete and properly executed as evidenced by:</p> <p>Patient #31 was a 65 year old female admitted to the hospital on 12/6/12. The patient's diagnosis included aortic valve stenosis, atrial fibrillation, and patent foramen ovale (PFO, a hole between left and right upper chambers of the heart). Her surgeries included aortic valve replacement, MAZE procedure (surgical procedure to treat rapid heart rate), and closure of the PFO.</p>	A 955	<p>The following actions were taken by the Director of Surgical Services who is also responsible for ongoing compliance with the corrective action:</p> <ul style="list-style-type: none"> <li>Policy PR 4 - Informed Consent was reviewed and no changes were needed.</li> <li>COR Surgeons and perioperative staff members were re-educated about requirements to have names of credentialed providers performing procedures on the Operative Invasive Procedure Consent Form #55-2559-dtd 12-2012.</li> <li>COR Surgeons and perioperative staff were re-educated about the requirement to include Significant Surgical Tasks, such as Endoscopic Vein Harvesting, on the Operative Invasive Procedure Consent Form(55-2559-dtd 12-2012)</li> <li>The "Reasons and Benefits" section of the Operative Invasive Procedure Consent Form #55-2559-dtd 12-2012 was revised to address these issues. The "Risks and Hazards" section of the Operative Invasive Procedure Consent Form #55-2559-dtd 12-2012 form was revised to address the associated risks and hazards.</li> <li>The PCC or designee will audit 100% of the COR surgical consent forms will be audited by the patient care coordinator prior to the initiation of the cardiac surgical procedure to assure appropriate and complete completion of the COR consent form. Monthly random chart audits will be utilized when 100% daily audits</li> </ul>	<p>12/10/12</p> <p>12/11/12</p> <p>12/14/12</p> <p>12/14/12</p> <p>12/14/12</p>

			<p>confirm continued compliance with documentation requirements, with no less than a one-month period of daily auditing.</p> <ul style="list-style-type: none"> <li>• Patient consents forms will be completed prior to procedure.</li> <li>• The Director of Surgical Services will report Chart Audit results to Department of Surgery Quality &amp; Safety Committee and the Quality &amp; Safety Committee who will be responsible to address any additional actions to be taken to ensure continued compliance. Compliance concerns, should they occur at any time, will be directed to the Director of Surgery and follow the Chain of Command to Chief of Surgery and ultimately Chief Medical Officer.</li> </ul>	<p>12/14/12</p> <p>12/14/12</p>
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A 955	<p>On 12/6/12 Patient #31 had surgery. The consent form included a boxed area for the names of the assisting physician and surgical assistant and the surgical task to be performed. This area was blank as was the surgical task box. The risk and hazards were not delineated; instead the physician wrote "discussed with patient".</p> <p>Patient #34 is a 67 year old male admitted to the hospital on 12/3/12. The patient diagnoses included coronary artery disease and right lower lobe lung nodule. The patient had surgery on 12/6/12. His surgery included quadruple coronary artery bypass grafting. The surgical consent form lacks the name of the assisting physician and the surgical assistant in the box provided and the surgical tasks to be performed were not written in the box. On the risk and benefit lines, the surgeon wrote "as discussed".</p> <p>Patient #35 was a 60 year old male admitted to the hospital on 12/5/12 with a diagnosis of</p>	A 955		
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A 955	<p>Atherosclerotic coronary artery disease. The patient had surgery on 12/6/12. His surgery included CABG x five vessels. The consent form lacks the names of the assisting physicians and surgical assistant, again the box is checked for unknown. The surgical task for the assisting physician was blank and in the block for the surgical assistant was written saphenous vein harvest. In the space for the risk and hazards of the procedure was written "discussed with patient and wife" but no specifics.</p> <p>According to interviews with other surgeons, Patients #34 and #35 signed the consent forms one to two days before the procedure which is why no names were placed in the assisting physician and surgical assistant block but the task to be performed should have been written in the box provided.</p> <p>According to the COMAR 10.32.16, Petition for</p>	A 955		

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A 955	Declaratory Ruling, the operative tasks and the persons delegated to perform those tasks should be delineated on the consent and informed consent should be obtained from the patient.	A 955		
	The hospital consent for cardiac surgery satisfies the requirements for informed consent regarding the tasks performed by unlicensed assistants, however, the hospital failed to ensure that the surgeons are using the form as designed,			
	See also Tag A-945			
A 959	482.51(b)(6) OPERATIVE REPORT	A 959		
	An operative report describing techniques, findings and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.			
	This STANDARD is not met as evidenced by:			

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A 959	<p>Based on review of the medical record, it was determined that the operative reports are incomplete since they lack a description of the specific significant surgical tasks conducted by practitioners other than the primary surgeon/practitioner, which includes harvesting grafts.</p> <p>In two open medical records reviewed for surgical patients (patients #34 and patient #35) the surgeons failed to identify the specific tasks that were performed by the physician assistant and the surgical assistant in the body of the operative report or intra-operative report.</p>	A 959	<p>The following actions were taken by the Director of Surgical Services who is also responsible for ongoing compliance with this corrective action:</p> <ul style="list-style-type: none"> <li>Reviewed the stated deficiency with the Chief of Surgery and the Chief of Cardiac Surgery</li> <li>The Chief of Cardiac Surgery was in-serviced regarding the need for accurate documentation of the significant surgical tasks performed by other practitioners involved in the case, such as Endoscopic Vein Harvesting by surgical assistants or physician assistants.</li> <li>COR Circulators were in-serviced regarding the need for accurate documentation of the tasks performed by the Physician Assistants on the intra-operative record.</li> <li>Staff and surgeons present were in-serviced about documentation requirements.</li> <li>Refresh staff prior to start of each case until all surgeons and circulators have implemented new documentation process.</li> </ul> <p>The PCC or designee is responsible for the following:</p> <ol style="list-style-type: none"> <li>100% of intra-operative documentation is audited for presence of significant surgical tasks by other practitioners on the day of surgery to assure appropriate completion of the COR documentation.</li> <li>Incomplete documentation is completed with</li> </ol>	<p>12/11/12</p> <p>12/10/12 - 12/12/12</p> <p>12/10/12 - 12/12/12</p> <p>12/10/12 - 12/12/12</p> <p>12/10/12 - 12/12/12</p> <p>12/12/12 and ongoing</p>

			<p>late entry process.</p> <ol style="list-style-type: none"> <li>3. Daily audits continue until 100% compliance is achieved and sustained for one month.</li> <li>4. Monthly chart audits will be utilized when daily audits demonstrate compliance with documentation requirements.</li> <li>5. 100% of physician operative documentation is audited for evidence of the techniques, findings and tissues removed or altered and the documentation of significant tasks performed by assistants during the operation.</li> </ol> <p>The Director of Surgical Services reports compliance results to Department of Surgery Quality and Safety Committee, Medical Executive Committee and the Board of Directors.</p>	Effective immediately
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K 000	<p><b>INITIAL COMMENTS</b></p> <p>On December 3, 2012 a Life Safety Code Survey Inspection was conducted at this facility for the purpose of determining compliance with Medicare/Medicaid requirements.</p> <p>Survey activities included observation of the physical environment, review of records, observation of staff practices, and interviews with staff members. Two facility maintenance supervisors escorted this surveyor or provided documentation during the survey.</p> <p>This facility is a seven story brick masonry building of Type 1 construction. In addition to the seven floors, the building has a Ground Level, a Basement and a flat roof with a heli-pad. The facility is fully automatic sprinkler protected.</p>	K 000		
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K 000	This surveyor found no evident violations of the Life Safety Code, NFPA 101, 2000 Edition, at the time of this survey. There are no objections to the certification of this facility.	K 000		
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